UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

OSMAN MUKELJIC, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. ALLARITY THERAPEUTICS, INC., THOMAS JENSEN, JAMES G. CULLEM, STEVE R. CARCHEDI, JOAN Y. BROWN, and JENS ERIK KNUDSEN, Defendants.	**Case No.** **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Osman Mukeljic ("Plaintiff"), individually and on behalf of all others similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Allarity Therapeutics, Inc. ("Allarity" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial, additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Allarity securities between

May 17, 2022 and July 19, 2024, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Allarity is a clinical-stage biopharmaceutical company that develops oncology therapeutics using drug-specific companion diagnostics generated by its Drug Response Predictor technology. Allarity's drug candidates include, *inter alia*, Dovitinib, a pan-tyrosine kinase inhibitor for the treatment of renal cell carcinoma ("RCC"). The Company's companion diagnostic technology for Dovitinib is referred to as "DRP®-Dovitinib" or "Dovitinib-DRP."

3. On April 2, 2021, Allarity's predecessor parent corporation, Allarity Therapeutics A/S ("Allarity A/S"), announced that it had submitted a premarket approval application ("PMA") to the U.S. Food and Drug Administration ("FDA") for Dovitinib-DRP (the "Dovitinib-DRP PMA").

4. On December 22, 2021, Allarity issued a press release announcing that it had submitted a new drug application ("NDA") to the FDA seeking marketing approval for Dovitinib for the third-line treatment of RCC patients (the "Dovitinib NDA").

5. On February 18, 2022, Allarity issued a press release announcing that it had received Refusal to File ("RTF") letters from the FDA for the Dovitinib NDA and the Dovitinib-DRP PMA because "the NDA . . . and the PMA application . . . were not sufficiently complete to permit substantive reviews," noting that "the FDA's cited reasons for the RTF decision primarily include[d], but [we]re not limited to, that submitted clinical trial data do not enable a conclusion of efficacy based on non-inferiority data set" and that, because "the PMA and NDA were filed as related applications, the RTFs also apply to the DRP®-Dovitinib companion diagnostic."

6. Following these developments, Allarity continued to represent to investors and the market that it remained committed to pursuing the Dovitinib NDA and would work with the FDA to determine a clear regulatory path forward for resubmitting that application.

7. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operations, and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Defendants had overstated the Dovitinib NDA's continued regulatory prospects; (ii) Allarity and three of its former officers had engaged in illegal, illicit, and/or otherwise improper conduct in connection with the Dovitinib NDA and/or the Dovitinib-DRP PMA; (iii) the foregoing misconduct subjected the Company to an increased risk of regulatory and/or governmental scrutiny and enforcement action, as well as significant legal, monetary, and reputational harm; (iv) following Allarity's announcement that it was, in fact, being investigated for wrongdoing in connection with the Dovitinib NDA and/or the Dovitinib-DRP PMA, the Company downplayed the substantial likelihood that an enforcement action would result from such investigation; and (v) as a result, the Company's public statements were materially false and misleading at all relevant times.

8. On June 29, 2022, Allarity issued a press release announcing that, "[e]ffective immediately," it had appointed Defendant James G. Cullem ("Cullem"), the Company's current Chief Business Officer ("CBO"), as its interim Chief Executive Officer ("CEO"), and Defendant Joan Y. Brown ("Brown"), the Company's current Director of Financial Reporting, as its interim Chief Financial Officer ("CFO"), and that its former CEO Defendant Steve R. Carchedi ("Carchedi") and former CFO Defendant Jens Knudsen ("Knudsen") had both purportedly "stepped down from those roles to pursue other opportunities."

9. The next day, Allarity disclosed in an SEC filing that Defendants Carchedi and Knudsen had either "resigned" or been "terminat[ed]" from all positions with the Company and its subsidiaries, while indicating that such "resignation" or "termination" may have been for cause, but without clarifying the same.

10. Following these disclosures, Allarity's stock price fell $0.31 per share, or 19.02%, to close at $1.32 per share on June 30, 2022.

11. On August 2, 2022, Allarity issued a press release announcing that "its Board of Directors has mandated a refocus of the Company's oncology pipeline strategy away from development of monotherapies" and, accordingly, "determined that advancing dovitinib as a monotherapy in adults is no longer commercially viable or in the best interests of its shareholders," citing "feedback that the Company recently received from the [FDA] from a Type C advisory meeting held in Q2 2022, regarding a potential Phase 3 clinical development path for dovitinib as a monotherapy third-line treatment for metastatic [RCC]." Accordingly, the Company would no longer pursue the Dovitinib NDA, which sought approval of Dovitinib as a monotherapy.

12. On this news, Allarity's stock price fell $0.045 per share, or 3.688%, to close at $1.175 per share on August 2, 2022.

13. On February 6, 2023, Allarity disclosed in an SEC filing that, "[i]n January 2023, we received a letter to produce documents from the SEC and that stated that the staff of the SEC is conducting an investigation . . . to determine if violations of the federal securities laws have occurred" in connection with "disclosures relating to submissions, communications and meetings with the FDA regarding our NDA for Dovitinib or Dovitinib-DRP."

14. On this news, Allarity's stock price fell $0.009 per share, or 3.8%, to close at $0.228 per share on February 6, 2023.

15. On December 11, 2023, Allarity disclosed in another SEC filing that, "[o]n December 8, 2023, [Defendant] Cullem was terminated as [CEO] of Allarity . . . and all other positions with the Company and its subsidiaries" and that Defendant Thomas Jensen ("Jensen") had been appointed as the Company's new CEO on the same date.

16. On this news, Allarity's stock price fell $0.075 per share, or 13.37%, to close at $0.486 per share on December 11, 2023.

17. Then, on July 22, 2024, Allarity disclosed in yet another SEC filing that it had received a Wells Notice[1] from the SEC's staff "relating to the Company's previously disclosed SEC investigation," advising that "[t]he Wells Notice relates to the Company's disclosures regarding meetings with the [FDA] regarding the Company's NDA for Dovitinib or Dovitinib-DRP, which was submitted to the FDA in 2021"; that, per the Company's understanding, "all conduct relating to the SEC Wells Notice occurred during or prior to fiscal year 2022"; and "that three of its former officers"—the same number of Company officers terminated during the Class Period—"received Wells Notices from the SEC relating to the same conduct."

18. On this news, Allarity's stock price fell $0.004 per share, or 2.38%, to close at $0.164 per share on July 22, 2024.

19. Finally, on September 13, 2024, Allarity disclosed in yet another SEC filing that, "[o]n September 12, 2024, the Company received a notice of resignation from [Defendant] Brown, its [CFO], effective September 12, 2024."

[1] A Wells Notice "is a communication from the [SEC] staff to a person involved in an investigation that: (1) informs the person the staff has made a preliminary determination to recommend that the Commission file an action or institute a proceeding against them; (2) identifies the securities law violations that the staff has preliminarily determined to include in the recommendation; and (3) provides notice that the person may make a submission to the Division and the Commission concerning the proposed recommendation." Office of Chief Counsel, SEC Division of Enforcement, Enforcement Manual § 2.4 at 19-20, https://www.sec.gov/divisions/enforce/enforcementmanual.pdf.

20. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

21. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

22. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

23. Venue is proper in this District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Allarity's common stock trades on the Nasdaq Stock Market ("NASDAQ"), which is located in this District.

24. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

25. Plaintiff, as set forth in the attached Certification, acquired Allarity securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

26. Defendant Allarity is a Delaware corporation with principal executive offices located at 24 School Street, 2nd Floor, Boston, Massachusetts 02108. Allarity's common stock trades in an efficient market on the NASDAQ under the ticker symbol "ALLR."

27. Defendant Jensen has served as Allarity's CEO since December 8, 2023.

28. Defendant Cullem served as Allarity's CEO from January 1, 2023 to December 8, 2023, before which he had served as the Company's interim CEO since June 29, 2022 and as the Company's CBO at all relevant times.

29. Defendant Carchedi served as Allarity's CEO and a Director of the Company from before the start of the Class Period to June 29, 2022.

30. Defendant Brown served as Allarity's CFO from January 1, 2023 to September 12, 2024, before which she had served as the Company's interim CFO since June 29, 2022.

31. Defendant Knudsen served as Allarity's CFO from before the start of the Class Period to June 27, 2022.

32. Defendants Jensen, Cullem, Carchedi, Brown, and Knudsen are collectively referred to herein as the "Individual Defendants."

33. The Individual Defendants possessed the power and authority to control the contents of Allarity's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Allarity's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Allarity, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

34. Allarity and the Individual Defendants are collectively referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS

Background

35. Allarity is a clinical-stage biopharmaceutical company that develops oncology therapeutics using drug-specific companion diagnostics generated by its Drug Response Predictor technology. Allarity's drug candidates include, *inter alia*, Dovitinib, a pan-tyrosine kinase inhibitor for the treatment of RCC. The Company's companion diagnostic technology for Dovitinib is referred to as "DRP®-Dovitinib" or "Dovitinib-DRP."

36. Allarity's assets, liabilities, and business operations initially belonged to its predecessor parent corporation Allarity A/S, a Danish *aktieselskab*, or stock-based corporation, which previously traded abroad on the Nasdaq First North Growth Market Sweden exchange. Allarity was formed as a direct wholly owned subsidiary of Allarity A/S for the purpose of consummating a reorganization that would eventually result in Allarity A/S's liquidation and dissolution, with Allarity becoming the parent holding company of substantially all of Allarity A/S's assets, liabilities, and business operations (the "Reorganization").

37. On April 2, 2021, Allarity A/S announced that it had submitted the Dovitinib-DRP PMA to the FDA.

38. On December 21, 2021, in connection with the Reorganization, Allarity began publicly trading in the U.S. on the NASDAQ.

39. The next day, on December 22, 2021, Allarity issued a press release announcing that it had submitted the Dovitinib NDA to the FDA.

40. On February 18, 2022, Allarity issued a press release announcing that the FDA "has provided the Company with [RTF] letters regarding the [NDA] for dovitinib, and its accompanying [PMA] application for the DRP®-Dovitinib companion diagnostic, for the third-line treatment of metastatic [RCC]." The Company advised that, "[u]pon preliminary review, the FDA determined that the NDA . . . and the PMA application . . . were not sufficiently complete to permit substantive reviews." The Company further advised that "[i]n the letter regarding the NDA, the FDA's cited reasons for the RTF decision primarily include[d], but [we]re not limited to, that submitted clinical trial data do not enable a conclusion of efficacy based on non-inferiority data set" and that, because "the PMA and NDA were filed as related applications, the RTFs also apply to the DRP®-Dovitinib companion diagnostic." Accordingly, the Company advised that it "intends to seek immediate guidance from the FDA, which potentially includes requesting a Type A meeting with the agency to clarify and respond to the issues identified in the RTF letters and seek additional guidance concerning information, data, and specific deliverables that the agency would require for a resubmitted NDA and PMA to be deemed complete."

41. On March 15, 2022, Allarity issued a press release providing an update on its Dovitinib program. Specifically, the Company announced that, "[f]ollowing several weeks of analysis by Company leadership together with clinical and regulatory experts, Allarity has now filed a formal request with the FDA for a 'Type C' meeting to further discuss potential clinical paths to support approval of dovitinib, together with its DRP®-Dovitinib companion diagnostic, in view of the FDA's recent RTFs" and that "[t]he Company anticipates providing a further update on the outcome of its FDA meeting and the future of the dovitinib program before the end of the third quarter of this year."

Materially False and Misleading Statements Issued During the Class Period

42. The Class Period begins on May 17, 2022. On May 16, 2022, during after-market hours, Allarity issued a press release announcing its fourth quarter and full year 2021 results (the "4Q/FY21 Press Release"). The 4Q/FY21 Press Release quoted Defendant Carchedi as stating, in relevant part:

> 2021 was a momentous year for Allarity . . . . As we await further feedback from the [FDA] regarding our NDA application for dovitinib, we remain steadfast in our mission to pair promising cancer therapeutics with our proprietary companion diagnostic technology to help significantly improve treatment outcomes for patients suffering from cancer. We look forward to sharing further updates on dovitinib . . . throughout the year.

43. In addition, the 4Q/FY21 Press Release asserted that "results of the Type C meeting with the FDA and outlining future development plans for dovitinib and its DRP®-Dovitinib companion diagnostic" as well as "[i]nitiation of prospective clinical study of dovitinib in metastatic [RCC] together with its DRP®-Dovitinib companion diagnostic" were "Anticipated Milestones [for the Company] in 2022[.]"

44. On May 17, 2022, Allarity filed an annual report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2021 (the "2021 10-K"). With respect to the Dovitinib NDA's continued regulatory prospects, as well as Allarity's communications with the FDA regarding the Dovitinib NDA and Dovitinib-DRP PMA, the 2021 10-K stated, *inter alia*:

> We submitted a[n NDA] to the [FDA) for our lead therapeutic candidate, dovitinib, a second-generation "pan"-tyrosine kinase inhibitor (TKI), on December 21, 2021, which was subsequently determined by the FDA to be not sufficiently complete to permit a substantive review and therefore was not accepted for filing. As discussed further below, we have requested a meeting with the FDA to discuss the nature and extent of additional clinical data, which is likely to include one or more additional clinical trials, that will be necessary to substantiate a complete NDA application. Concurrently with the FDA's conclusion on our NDA, the FDA also made a similar

determination on our application for a PMA on our companion diagnostic for dovitinib.

* * *

As mentioned above, we submitted an NDA with the FDA on December 21, 2021, for the third line treatment of metastatic [RCC] (mRCC or kidney cancer) in patients selected by our Dovitinib-DRP® companion diagnostic. Prior to submission of the NDA, we submitted a [PMA] application to the FDA for approval of our dovitinib-specific DRP® companion diagnostic for use to select and treat patients likely to respond to dovitinib. On February 15, 2022, we received [RTF] letters for both our dovitinib NDA and our DRP®-Dovitinib companion diagnostic PMA. The FDA has asserted that neither our NDA or PMA meets the regulatory requirements to warrant a complete agency review. The primary grounds of rejection asserted by the FDA relates to Allarity's use of prior Phase 3 clinical trial data, generated by Novartis in a "superiority" endpoint study against sorafenib (Bayer), to support a "non-inferiority" endpoint in connection with the DRP®-Dovitinib companion diagnostic. Allarity anticipates that it may be necessary to conduct a new, prospective Phase 3 study, to gain approval of dovitinib in the U.S. The Company plans to have discussions with the FDA during the second quarter of 2022 to clarify a path forward for approval of this lead program.

45. In addition, the 2021 10-K provided generic, boilerplate representations regarding the risk that Allarity's employees "may" or "could" engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, while simultaneously downplaying the same, stating, in relevant part:

We are exposed to the risk that our employees . . . ***may*** engage in fraudulent conduct or other illegal activity. Misconduct by these parties ***could*** include intentional, reckless or negligent conduct or unauthorized activities that violates [*inter alia*] . . . the laws and regulations of the FDA . . . and other similar regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, . . . federal and state . . . fraud and abuse and other healthcare laws and regulations in the U.S. and abroad and . . . laws that require the true, complete and accurate reporting of financial information or data . . . . Misconduct by these parties ***could*** also involve the improper use of individually identifiable information, including information obtained during clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of therapeutic candidates, which ***could*** result in regulatory sanctions and serious harm to our reputation.

Although ***we have adopted a Code of Business Conduct and Ethics***, it is not always possible to identify and deter misconduct by employees and other third parties, and

> ***the precautions we take to detect and prevent this activity may*** not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to follow such laws or regulations. Additionally, we are subject to the risk that a person or government ***could*** allege such fraud or other misconduct, ***even if none occurred***. ***If*** any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions ***could*** have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm and the delay, reduction, termination or restructuring of our operations.

(Emphases added.) Plainly, the foregoing risk warnings were generic, catch-all provisions that were not tailored to Allarity's actual known risks regarding the Company's and its employees' misconduct, much less that the Company and three of its former officers had engaged in illegal, illicit, and/or otherwise improper conduct in connection with the Dovitinib NDA and/or the Dovitinib-DRP PMA, which subjected the Company to an increased risk of regulatory and/or governmental scrutiny and enforcement action, as well as significant legal, monetary, and reputational harm.

46. Appended as exhibits to the 2021 10-K were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), wherein Defendants Carchedi and Knudsen certified, in relevant part, that the 2021 10-K "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report[.]"

47. The statements referenced in ¶¶ 42-46 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Defendants

had overstated the Dovitinib NDA's continued regulatory prospects; (ii) Allarity and three of its former officers had engaged in illegal, illicit, and/or otherwise improper conduct in connection with the Dovitinib NDA and/or the Dovitinib-DRP PMA; (iii) the foregoing misconduct subjected the Company to an increased risk of regulatory and/or governmental scrutiny and enforcement action, as well as significant legal, monetary, and reputational harm; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

The Truth Begins to Emerge

48. On June 29, 2022, during after-market hours, Allarity issued a press release announcing that, "[e]ffective immediately, the Company's Board of Directors has appointed [Defendant] Cullem, J.D., current [CBO], as interim [CEO] and [Defendant] Brown, CPA, current Director of Financial Reporting, as interim [CFO]" and that "[f]ormer CEO [Defendant] Carchedi and CFO [Defendant] Knudsen have stepped down from those roles to pursue other opportunities."

49. On June 30, 2022, Allarity filed a current report on Form 8-K with the SEC, notifying investors that Defendants Carchedi and Knudsen had either "resigned" or been "terminat[ed]" from all positions with the Company and its subsidiaries, while indicating that such "resignation" or "termination" may have been for cause, but without clarifying the same, stating, in relevant part:

> Effective as of June 29, 2022, [Defendant] Carchedi ***resigned*** from all positions in Allarity . . . and all positions of its subsidiaries, including his role of [CEO] and as a director of the Company. Pursuant to the terms set forth in a letter agreement dated June 24, 2022 (the "Carchedi Separation Agreement"), the ***termination*** of [Defendant] Carchedi's employment and ***resignation*** from his positions are effective June 29, 2022 (the "Carchedi Separation Date") . . . . In exchange for the Carchedi Severance Benefits, among other things as set forth in the Carchedi Separation Agreement, ***[Defendant] Carchedi agreed to a release of claims in favor of the Company*** . . . . In addition, as of the Carchedi Separation Date, ***[Defendant] Carchedi's unvested options were terminated*** . . . . ***[Defendant] Carchedi's resignation as a director was not the result of any dispute or***

> ***disagreement with the Company or the Company's Board of Directors on any matter relating to the operations, policies or practices of the Company.***
>
> Effective as of June 27, 2022, [Defendant] Knudsen ***resigned*** from all positions in the Company, and all positions of its subsidiaries, including his role of [CFO] of the Company. Pursuant to the terms set forth in a letter agreement dated June 25, 2022 (the "Knudsen Separation Agreement"), the ***termination*** of [Defendant] Knudsen's employment and ***resignation*** from his positions are effective June 27, 2022 (the "Knudsen Separation Date") . . . . In exchange for the Knudsen Severance Benefits, among other things as set forth in the Knudsen Separation Agreement, ***[Defendant] Knudsen agreed to a release of claims in favor of the Company*** . . . . In addition, as of the Knudsen Separation Date ***[Defendant] Knudsen's unvested options were terminated.***

(Emphases added.) Notably, although the foregoing disclosures represented that "[Defendant] Carchedi's resignation ***as a director*** was not the result of any dispute or disagreement with the Company or the Company's Board of Directors on any matter relating to the operations, policies or practices of the Company" (emphasis added), a similar representation was not made for Defendant Carchedi's resignation as CEO, nor was any such representation made for Defendant Knudsen.

50. Following these disclosures, Allarity's stock price fell $0.31 per share, or 19.02%, to close at $1.32 per share on June 30, 2022.

51. On August 2, 2022, during pre-market hours, Allarity issued a press release disclosing that it would no longer seek approval of Dovitinib as a monotherapy following additional communications with the FDA, stating, in relevant part:

> Allarity['s] . . . Board of Directors has mandated a refocus of the Company's oncology pipeline strategy away from development of monotherapies towards development of more promising and clinically relevant combination therapies.
>
> * * *
>
> The Board's decision . . . takes into account feedback that the Company recently received from the [FDA] from a Type C advisory meeting held in Q2 2022, regarding a potential Phase 3 clinical development path for dovitinib as a monotherapy third-line treatment for metastatic [RCC] (mRCC). As part of that

> feedback, the FDA has indicated, under its recent Project Optimus guidelines relating to new optimization of therapeutic dosing, that the Company will likely need to conduct a new dosing study for dovitinib prior to Company conducting any future Phase 3 studies that could enable the submission of a new NDA. Conducting a new dosing study for dovitinib, if required, would further delay the initiation and completion of a future Phase 3 study, and increase the cost, time, and market risks of advancing dovitinib as a monotherapy in the increasingly competitive indication of third-line mRCC. In view of those delays and increased costs/risks, the Company has determined that advancing dovitinib as a monotherapy in adults is no longer commercially viable or in the best interests of its shareholders.

Accordingly, the Company would no longer pursue the Dovitinib NDA, which sought approval of Dovitinib as a monotherapy.

52. On this news, Allarity's stock price fell $0.045 per share, or 3.688%, to close at $1.175 per share on August 2, 2022.

53. Then, on February 6, 2023, during pre-market hours, Allarity filed a current report on Form 8-K with the SEC (the "2023 8-K"), disclosing that the SEC was investigating the Company for potential violations of the federal securities laws in connection with the Company's disclosures regarding the Dovitinib NDA and/or the Dovitinib-DRP PMA, stating, in relevant part:

> In January 2023, we received a letter to produce documents from the SEC and that stated that the staff of the SEC is conducting an investigation known as "In the Matter of Allarity Therapeutics, Inc." to determine if violations of the federal securities laws have occurred. The documents requested appear to focus on disclosures relating to submissions, communications and meetings with the FDA regarding our NDA for Dovitinib or Dovitinib-DRP.

54. On this news, Allarity's stock price fell $0.009 per share, or 3.8%, to close at $0.228 per share on February 6, 2023.

55. Despite the foregoing declines in Allarity's stock price on June 30, 2022, August 2, 2022, and February 6, 2023 the Company's securities continued trading at artificially inflated prices throughout the remainder of the Class Period because of Defendants' continued misstatements and/or omissions regarding Allarity and its former officers' illegal, illicit, and/or

otherwise improper conduct in connection with the Dovitinib NDA and/or the Dovitinib-DRP PMA; the increased risk of regulatory and/or governmental scrutiny and enforcement action, as well as significant legal, monetary, and reputational harm, that this subjected the Company to; and the substantial likelihood that an enforcement action would result from the disclosed SEC investigation.

56. For example, the 2023 8-K downplayed the substantial likelihood that an enforcement action would result from the disclosed SEC investigation, stating, in relevant part:

> The SEC letter . . . stated that investigation is a fact-finding inquiry and does not mean that that the SEC has concluded that the Company or anyone else has violated the laws. We do not know when the SEC's investigation will be concluded or what action, ***if any***, ***might*** be taken in the future by the SEC or its staff as a result of the matters that are the subject to its investigation or what impact, ***if any***, the cost of continuing to respond to inquiries ***might*** have on our financial position or results of operations.

(Emphases added.)

57. On March 13, 2023, Allarity filed an annual report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2022 (the "2022 10-K"). The 2022 10-K downplayed the substantial likelihood that an enforcement action would result from the SEC investigation disclosed in the 2023 8-K, stating, in relevant part:

> ***We received a request for documents from the SEC in the investigation known as "In the Matter of Allarity Therapeutics, Inc.," the consequences of which are unknown.***
>
> In January 2023, we received a request to produce documents from the SEC that stated that the staff of the SEC is conducting an investigation known as "In the Matter of Allarity Therapeutics, Inc." to determine if violations of the federal securities laws have occurred. The documents requested appear to focus on submissions, communications and meetings with the FDA regarding our NDA for Dovitinib or Dovitinib-DRP. ***The SEC letter also stated that investigation is a fact-finding inquiry and does not mean that that the SEC has concluded that the Company or anyone else has violated the laws.***

> We do not know when the SEC's investigation will be concluded or what action, ***if any, might*** be taken in the future by the SEC or its staff as a result of the matters that are the subject to its investigation or what impact, ***if any***, the cost of continuing to respond to inquiries might have on our financial position or results of operations. ***We have not established any provision for losses in respect of this matter*** . . . . This investigation ***may*** result in significant legal expenses, the diversion of management's attention from our business, ***could*** cause damage to our business and reputation, and ***could*** subject us to a wide range of remedies, including enforcement actions by the SEC. There can be no assurance that any final resolution of this or any similar matters will not have a material adverse effect on our financial condition or results of operations.

(First emphasis in original.)

58. Appended as exhibits to the 2022 10-K were substantively the same SOX certifications as referenced in ¶ 46, *supra*, signed by Defendants Cullem and Brown.

59. The statements referenced in ¶¶ 56-58 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Allarity and three of its former officers had engaged in illegal, illicit, and/or otherwise improper conduct in connection with the Dovitinib NDA and/or the Dovitinib-DRP PMA; (ii) the foregoing misconduct subjected the Company to an increased risk of regulatory and/or governmental scrutiny and enforcement action, as well as significant legal, monetary, and reputational harm; (iii) following Allarity's announcement that it was, in fact, being investigated for wrongdoing in connection with the Dovitinib NDA and/or the Dovitinib-DRP PMA, the Company downplayed the substantial likelihood that an enforcement action would result from such investigation; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

60. On December 11, 2023, during pre-market hours, Allarity filed a current report on Form 8-K with the SEC, disclosing that, "[o]n December 8, 2023, [Defendant] Cullem was

terminated as [CEO] of Allarity . . . and all other positions with the Company and its subsidiaries" and that Defendant Jensen had been appointed as the Company's new CEO on the same date.

61. On this news, Allarity's stock price fell $0.075 per share, or 13.37%, to close at $0.486 per share on December 11, 2023. Despite this decline in Allarity's stock price, the Company's securities continued trading at artificially inflated prices throughout the remainder of the Class Period because of Defendants' continued misstatements and/or omissions regarding Allarity and its former officers' illegal, illicit, and/or otherwise improper conduct in connection with the Dovitinib NDA and/or the Dovitinib-DRP PMA; the increased risk of regulatory and/or governmental scrutiny and enforcement action, as well as significant legal, monetary, and reputational harm, that this subjected the Company to; and the substantial likelihood that an enforcement action would result from the disclosed SEC investigation.

62. For example, on March 8, 2024, Allarity filed an annual report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2023 (the "2023 10-K"). The 2023 10-K contained the same statements as referenced in ¶ 57, *supra*, downplaying the substantial likelihood that an enforcement action would result from the SEC investigation disclosed in the 2023 8-K.

63. Appended as exhibits to the 2023 10-K were substantively the same SOX certifications as referenced in ¶ 46, *supra*, signed by Defendants Jensen and Brown.

64. The statements referenced in ¶¶ 62-63 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Allarity and three of its former officers had engaged in illegal, illicit, and/or otherwise improper conduct in

connection with the Dovitinib NDA and/or the Dovitinib-DRP PMA; (ii) the foregoing misconduct subjected the Company to an increased risk of regulatory and/or governmental scrutiny and enforcement action, as well as significant legal, monetary, and reputational harm; (iii) following Allarity's announcement that it was, in fact, being investigated for wrongdoing in connection with the Dovitinib NDA and/or the Dovitinib-DRP PMA, the Company downplayed the substantial likelihood that an enforcement action would result from such investigation; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

The Truth Fully Emerges

65. On July 22, 2024, during pre-market hours, Allarity filed a current report on Form 8-K with the SEC (the "2024 8-K"), disclosing that it had received a Wells Notice from the SEC's staff "relating to the Company's previously disclosed SEC investigation." In particular, the 2024 8-K stated, in relevant part:

> On July 19, 2024, Allarity . . . received a "Wells Notice" from the Staff of the [SEC] relating to the Company's previously disclosed SEC investigation. The Wells Notice relates to the Company's disclosures regarding meetings with the [FDA] regarding the Company's NDA for Dovitinib or Dovitinib-DRP, which was submitted to the FDA in 2021. The Company understands that all conduct relating to the SEC Wells Notice occurred during or prior to fiscal year 2022. Allarity also understands that three of its former officers received Wells Notices from the SEC relating to the same conduct. A Wells Notice is neither a formal charge of wrongdoing nor a final determination that the recipient has violated any law. The Wells Notice informed the Company that the SEC Staff has made a preliminary determination to recommend that the SEC file an enforcement action against the Company that would allege certain violations of the federal securities laws.

66. On this news, Allarity's stock price fell $0.004 per share, or 2.38%, to close at $0.164 per share on July 22, 2024.

67. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

Post-Class Period Developments

68. On September 13, 2024, Allarity filed a current report on Form 8-K with the SEC, disclosing that, "[o]n September 12, 2024, the Company received a notice of resignation from [Defendant] Brown, its [CFO], effective September 12, 2024."

Regulation S-K Items 105 & 303

69. Throughout the Class Period, Allarity's periodic financial filings were required to disclose the adverse facts and circumstances detailed above under applicable SEC rules and regulations. Specifically, Item 105 of SEC Regulation S-K, 17 CFR § 229.105 ("Item 105"), required Allarity to "provide under the caption 'Risk Factors' a discussion of the material factors that make an investment in the [Company] or offering speculative or risky" and "[c]oncisely explain how each risk affects the [Company] or the securities being offered." Defendants' failures to disclose, *inter alia*, the Company's and its former officers' misconduct in connection with the Dovitinib NDA and/or the Dovitinib-DRP PMA, the increased risk of regulatory and/or governmental scrutiny and enforcement action, as well as significant legal, monetary, and reputational harm, that this subjected the Company to, and the substantial likelihood that an enforcement action would result from the SEC's investigation violated Item 105 because these issues represented material factors that made an investment in the Company speculative or risky.

70. For similar reasons, Defendants violated Item 303 of SEC Regulation S-K, 17 C.F.R. § 229.303(b)(2)(ii) ("Item 303"), which required the Company to "[d]escribe any known trends or uncertainties that have had or that are reasonably likely to have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations." Defendants' failures to disclose the true continued regulatory prospects for the Dovitinib NDA, the Company's and its former officers' misconduct in connection with the Dovitinib NDA and/or the Dovitinib-

DRP PMA, the increased risk of regulatory and/or governmental scrutiny and enforcement action, as well as significant legal, monetary, and reputational harm, that this subjected the Company to, and the substantial likelihood that an enforcement action would result from the SEC's investigation violated Item 303 because these issues represented known trends and uncertainties that were likely to have a material unfavorable impact on the Company's business and financial results.

SCIENTER ALLEGATIONS

71. During the Class Period, Defendants had both the motive and opportunity to commit fraud. They also had actual knowledge of the misleading nature of the statements they made, or acted in reckless disregard of the true information known to them at the time. Indeed, during the Class Period, three of Allarity's former executives—the same number of former Company executives that Allarity disclosed had received an SEC Wells Notice in connection with the Dovitinib NDA—serving in their roles as CEO, CFO, and/or CBO, were terminated from all positions with the Company and its subsidiaries, presumably as a result of the wrongdoing alleged herein. Accordingly, Defendants participated in a scheme to defraud and committed acts, practices, and participated in a course of business that operated as a fraud or deceit on purchasers of the Company's securities during the Class Period.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

72. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Allarity securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate

families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

73. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Allarity securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Allarity or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

74. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

75. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

76. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Allarity;

- whether the Individual Defendants caused Allarity to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Allarity securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

77. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

78. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Allarity securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Allarity securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

79. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

80. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

81. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

82. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

83. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Allarity securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Allarity

securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

84. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Allarity securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Allarity's finances and business prospects.

85. By virtue of their positions at Allarity, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

86. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Allarity, the Individual Defendants had knowledge of the details of Allarity's internal affairs.

87. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Allarity. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Allarity's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Allarity securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Allarity's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Allarity securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

88. During the Class Period, Allarity securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Allarity securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Allarity securities was substantially lower than the prices paid by Plaintiff and the other

members of the Class. The market price of Allarity securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

89. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

90. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

91. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

92. During the Class Period, the Individual Defendants participated in the operation and management of Allarity, and conducted and participated, directly and indirectly, in the conduct of Allarity's business affairs. Because of their senior positions, they knew the adverse non-public information about Allarity's misstatement of income and expenses and false financial statements.

93. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Allarity's financial condition and results of operations, and to correct promptly any public statements issued by Allarity which had become materially false or misleading.

94. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Allarity disseminated in the marketplace during the Class Period concerning Allarity's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Allarity to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Allarity within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Allarity securities.

95. Each of the Individual Defendants, therefore, acted as a controlling person of Allarity. By reason of their senior management positions and/or being directors of Allarity, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Allarity to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Allarity and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

96. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Allarity.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: September 13, 2024

Respectfully submitted,

POMERANTZ LLP

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